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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/550,667

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Jean-Philippe Starck

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8348

20306

7590

02/03/2009

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EXAMINER

YOUNG, SHAWQUA

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

02/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/550,667	Applicant(s) STARCK ET AL.	
	Examiner SHAWQUIA YOUNG	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-11 and 18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8,9,11 and 18 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/10/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-6, 8-11 and 18 are currently pending in the instant application. Applicants have cancelled claims 7, 15 and 17 in an amendment filed on November 10, 2008.

I. *Response to Arguments*

Applicants' amendment, filed on November 10, 2008, has overcome the rejection of claims 1-6, 8-11 and 18 under 35 USC 103(a) as being unpatentable over Morozov, et al.; the rejection of claims 15 and 17 under 103 as being unpatentable over Macias; the rejection of claim 15 under 35 USC 102(b) as being anticipated by Tius, et al.; Ganellin, and Smith references; the objection of claim 1; the objection of claims 11 and 17. The above rejections and objections have been withdrawn. The Examiner has fully considered the declaration filed on November 10, 2008.³

II. *Information Disclosure Statement*

The information disclosure statement (IDS) submitted on November 10, 2008 is in partial compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been partially considered by the examiner.

III. *Rejection(s)*

35 USC § 103 - OBVIOUSNESS REJECTION

The following is a quotation of 35 U.S.C. § 103(a) that forms the basis for all

Art Unit: 1626

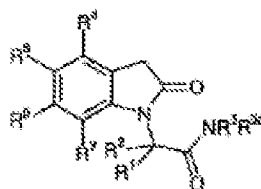
obviousness rejections set forth in this Office action:

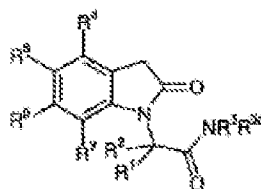
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Graham v. John Deere Co. set forth the factual inquiries necessary to determine obviousness under 35 U.S.C. § 103(a). See *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Specifically, the analysis must employ the following factual inquiries:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 8, 9, 11 and 18 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Morozov, et al.* (SU 841 264 A1) in view of Silverman (1992).



Applicants claim a compound of formula  wherein R¹ is hydrogen; R² is hydrogen or C₁₋₂₀ alkyl; R³ is hydrogen, C₁₋₂₀ alkyl, C₄₋₈ cycloalkyl, C₅₋₈ cycloalkenyl, aryl, C₁₋₂₀ alkoxy or a group of formula –W–R⁸; R^{3a} is hydrogen or C₁₋₂₀ alkyl; R⁴ is hydrogen; R⁵ is as defined in claim 1; R⁶ is hydrogen, C₁₋₂₀ alkyl or halogen; R⁷ is hydrogen, C₁₋₂₀ alkyl or halogen, W is C₁₋₁₂ alkylene, –NH– or –NHC(=O) and R⁸ is

Art Unit: 1626

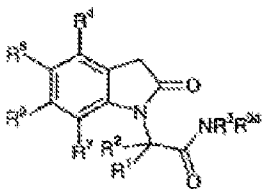
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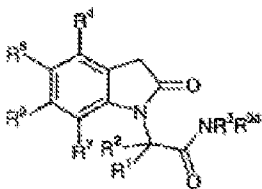
The Scope and Content of the Prior Art (MPEP §2141.01)

Morozov, et al. teaches 2,3-dihydro-2-oxo-1H-indole-1-acetamide and that it possesses anticonvulsive activity. Silverman teaches drug development which includes structure modifications to increase potency and therapeutic index (i.e. bioisosterism). Specifically, Silverman teaches that Fluorine is a nonclassical bioisostere of hydrogen.

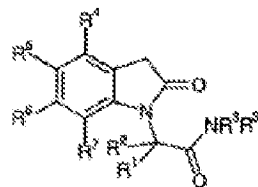
The Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of *Morozov, et al.* and the instant invention is that there is homologous subject matter. The instant claims are drawn to a compound



of the formula  wherein all variables can be hydrogen except for R⁵ which is a halogen or a trifluoromethyl group whereas the prior art reference teaches a similar compound but the 6-position of the indolone ring (equivalent to Applicants' R⁵) is unsubstituted.

Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)



Applicants are claiming a compound of the formula

wherein R⁵ is a halogen or trifluoromethyl and R¹, R², R³, R^{3a}, R⁴, R⁶ and R⁷ can be hydrogen atoms. The prior art reference of *Morozov, et al.* teaches a similar compound 2,3-dihydro-2-oxo-1H-indole-1-acetamide which does not have any substituents present.

According to Silverman, it is well known in the art that bioisosterism is a lead modification approach that has been shown to be useful to attenuate toxicity or to modify the activity of a lead compound. Bioisosteres are substituents or groups that have chemical or physical similarities and which produce broadly similar biological properties. In table 2.3 on page 17, Silverman teaches that hydrogen and fluorine are considered nonclassical bioisosteres which means that the two groups can be interchanged in a lead compound and will produce broadly similar biological properties. It would have been obvious within one of ordinary skill in the art to try to prepare additional compounds by interchanging a hydrogen atom with a fluorine atom or another halogen atom in the lead compound disclosed in *Morozov, et al.* based on the modification approach of bioisosterism to try to modify the biological activity. Utilizing bioisosterism during the drug development process is well known in the art and is considered routine modification and within one skilled in the art. A strong prima facie obviousness has been established.

Art Unit: 1626

IV. Objections

Dependent Claim Objections

Dependent Claim 10 is objected to as being dependent upon a rejected based claim. To overcome this objection, Applicant should rewrite said claims in an independent form and include the limitations of the base claim and any intervening claim.

V. Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/550,667

Page 7

Art Unit: 1626

/Shawquia Young/

Examiner, Art Unit 1626

/Rebecca L Anderson/

Primary Examiner, Art Unit 1626